

IN THE UNITED STATES DISTRICT COURT  
FOR THE NORTHERN DISTRICT OF GEORGIA  
ATLANTA DIVISION

IN RE STAND 'N SEAL,  
PRODUCTS LIABILITY  
LITIGATION

MDL DOCKET NO. 1804  
ALL CASES

1:07 MD1804-TWT

ORDER

This is an MDL proceeding in which about 200 personal injury actions are consolidated for pretrial proceedings. For the reasons stated below, the Defendants' Motion for Summary Judgment on the Issue of General Causation [Doc. 1367] is DENIED; the Defendants' Motions to Exclude the Testimony of David Hurst [Doc. 1438, 1850] are DENIED; the Defendants' Motions to Exclude the Testimony of Henry Spiller [Doc. 1763, 1851] are DENIED; the Defendant's Motion to Exclude the Testimony of Roger Wabeke [Doc. 1852] is DENIED; the Defendants' Motion to Exclude the Affidavit of Henry Spiller [Doc. 2098] is DENIED; the Defendants' Motion to Exclude the Affidavit of David Hurst [Doc. 2103] is GRANTED IN PART and DENIED IN PART; and the Defendants' Motion to Exclude the Affidavit of Roger Wabeke [Doc. 2107] is DENIED.

## I. Background

This MDL proceeding arises out of lawsuits filed by users of Stand ‘n Seal “Spray-On” Grout Sealer. Stand ‘n Seal is a consumer product used to seal ceramic tile grout in kitchens, bathrooms, and similar areas. The purported advantage of Stand ‘n Seal is that users can easily stand and spray the sealant onto the grout without the strain of using a brush and manually applying the sealant. The Plaintiffs say that the problems with Stand ‘n Seal began when the manufacturer changed its chemical components. Stand ‘n Seal was originally manufactured with a fluoropolymer chemical known as Zonyl 225.<sup>1</sup> But from April to May 2005, and again in July 2005, the manufacturer of Stand ‘n Seal switched from Zonyl to a different fluoropolymer chemical known as Flexipel S-22WS. The Plaintiffs say that users of Stand ‘n Seal immediately began experiencing respiratory problems, such as chemical pneumonitis, from exposure to Stand ‘n Seal. By August 31, 2005, Stand ‘n Seal with Flexipel was recalled.

As a result of their injuries, consumers all over the country filed lawsuits asserting various claims against each of the companies involved in the manufacture,

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<sup>1</sup>Fluoropolymers are known for exceptional chemical resistance and high-temperature stability. The most commonly known fluoropolymer is probably the DuPont brand Teflon. Teflon is used in hundreds of products, including coating of non-stick frying pans.

distribution, and sale of Stand 'n Seal with Flexipel. On January 5, 2007, the Judicial Panel on Multidistrict Litigation transferred the federal lawsuits to this Court for consolidated pretrial proceedings. This MDL proceeding has now been pending for over two years. During that time, both sides have submitted numerous pleadings and engaged in extensive discovery. The Defendants now move for summary judgment on general causation as to all of the claims asserted by the Plaintiffs. The Defendants also move to exclude testimony and affidavits from the Plaintiffs' experts David Hurst, Henry Spiller, and Roger Wabeke.

## II. Summary Judgment Standard

Summary judgment is appropriate only when the pleadings, depositions, and affidavits submitted by the parties show that no genuine issue of material fact exists and that the movant is entitled to judgment as a matter of law. Fed.R.Civ.P. 56(c). The court should view the evidence and any inferences that may be drawn in the light most favorable to the non movant. Adickes v. S.H. Kress and Co., 398 U.S. 144, 158-159 (1970). The party seeking summary judgment must first identify grounds that show the absence of a genuine issue of material fact. Celotex Corp. v. Catrett, 477 U.S. 317, 323-24 (1984). The burden then shifts to the non-movant, who must go beyond the pleadings and present affirmative evidence to show that a genuine issue of material fact exists. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 257 (1986).

### III. Discussion

Because the admissibility of testimony and affidavits from the Plaintiffs' experts affects whether the Defendants are entitled to summary judgment, the Court will discuss the Defendants' motions to exclude before the motion for summary judgment.

#### A. Expert Affidavits

The Defendants move to exclude the affidavits from the Plaintiffs' experts David Hurst, Henry Spiller, and Roger Wabeke. These affidavits were submitted by the Plaintiffs after the Defendants filed motions to exclude testimony by these experts. The Defendants say that the affidavits should be excluded because they contain new opinions not disclosed during discovery and that the affidavits violate the "sham affidavit" rule. Under the sham affidavit rule, "[w]hen a party has given clear answers to unambiguous questions which negate the existence of any genuine issue of material fact, that party cannot thereafter create such an issue with an affidavit that merely contradicts, without explanation, previously given clear testimony." Van T. Junkins & Assocs., Inc. v. U.S. Industries, Inc., 736 F.2d 656, 657 (11th Cir. 1984). The requirements for applying the sham affidavit rule are very stringent, and the Defendants have not demonstrated that those requirements are met in this case. For all of the statements that the Defendants say violate the sham affidavit rule, the

Defendants have not shown that the questions were unambiguous, that the answers were clear, or that there is no explanation for any alleged contradiction. It is true that there are some discrepancies between the depositions of Hurst, Spiller, and Wabeke, and their affidavits. But those are simply “discrepancies which create an issue of credibility or go to the weight of the evidence.” Tippens v. Celotex Corp., 805 F.2d 949, 953 (11th Cir. 1986). Therefore, the affidavits from Hurst, Spiller, and Wabeke should not be excluded under the sham affidavit rule.

The Defendants also say that the affidavits should be excluded because the affidavits contain new expert opinions that were not disclosed in the expert reports or depositions. Under Rule 26 of the Federal Rules of Civil Procedure, “a party must disclose to the other parties the identity of any witness it may use at trial to present evidence under [the expert witness rules].” Fed. R. Civ. P. 26(a). This disclosure must be accompanied by a written report, and the written report must contain, among other things, “a complete statement of all opinions the witness will express and the basis and reasons for them.” Fed. R. Civ. P. 26(b)(i). The reason for the expert disclosure rule is “to provide opposing parties reasonable opportunity to prepare for effective cross examination and perhaps arrange for expert testimony from other witnesses.” Reese v. Herbert, 527 F.3d 1253, 1265 (11th Cir. 2008). The Court will discuss each affidavit separately.

1. David Hurst

After careful review of David Hurst's expert report, deposition testimony, and affidavit, only paragraph 13 of Hurst's affidavit appears to be a new opinion. In paragraph 13, Hurst says that:

My ninth opinion is that offering Stand 'n Seal as a brushed on product would make it safer. I agreed during my deposition that there would need to be testing of the product as a brush on. That testing, however, can take many forms. For example, I personally conducted such testing because I applied the product as both a spray and a brush on. When I painted the material, I was able to operate without any type of mask and there were no airborne particles released that could have been inhaled. When I sprayed the materials, while wearing a mask, it produced a significant amount of airborne particles. Further, although testing would need to be performed before the product would be placed on the market as a brush on; there is no real chance for respirable size particles being released in a brush on application. I can state within a reasonable degree of scientific probability that using this product as a brush on would essentially eliminate the risk of inhaling the fluoropolymers contained in the product.

(Hurst. Aff. ¶ 13.) Until his affidavit, Hurst had never disclosed that he had personally tested Stand 'n Seal as a brush on product. Hurst had also never disclosed his opinion that there is no real chance that applying Stand 'n Seal as a brush on product would release respirable size particles. These statements should have been included in Hurst's expert report or deposition testimony. See Palmer v. Asarco Inc., No. 03-CV-0498, 2007 WL 2254343, at \*3 (N.D. Okla. Aug. 3, 2007). The Plaintiffs, however, say that any new statements in Hurst's affidavit should be considered as a

supplemental disclosure. Rule 26 allows a party to supplement its disclosures if “the party learns that in some material respect the disclosure or response is incomplete or incorrect.” Fed. R. Civ. P. 26(e). The Court will allow this portion of the affidavit as a supplementation to the Plaintiffs’ previous disclosures. The Defendants may take a supplemental discovery deposition of Mr. Hurst, limited to the subject matter of this testing and the related opinions, lasting no more than two hours.

The rest of Hurst’s affidavit is not new and should not be excluded. Although the statements in Hurst’s affidavit are not identical to the statements in his expert report, they “[do] not differ substantially.” Rowe Int’l Corp. v. Ecast, Inc., 586 F. Supp. 2d 924, 935 (N.D. Ill. 2008). For example, in his affidavit, Hurst says that:

My fifth, sixth, and seventh opinions regard the necessity for quality control in the polymerization process to reduce the residual monomers. Based on the information I was provided about the polymerization process of Flexipel S-22WS, there was not a test for residual monomers. I was not, however, provided details of the polymerization process. Consequently, it is possible that such a quality control measure exists in the process. My opinions in this case are that a reasonable polymer producer will have quality control procedures in place to ensure the reduction of residual monomers, especially when dealing with [fluoropolymers] that present a significant risk of harm. I never stated that the manufacturers of Flexipel S-22WS did or did not have the necessary quality control procedures in their polymerization process. I have merely stated that from the testimony I have read and what I have been provided, no such quality control procedure exists. The motions attempting to exclude my opinions appear to misunderstand my opinions, in this regard. My opinions are as to what a prudent manufacturer of fluoropolymers will do in the polymerization process. I have not attempted to provide an opinion within a reasonable degree of scientific

probability that the manufacturers failed to have adequate quality control processes in place, because that is a factual dispute based on testimony of witnesses, not scientific analysis.

(Hurst Aff. ¶ 11.) The Defendants say that, before his affidavit, Hurst never qualified his opinions with statements like “I have merely stated that from the testimony I have read and what I have been provided” and “what a prudent manufacturer will do.” But Hurst did qualify his opinions in his expert report with similar language. In his expert report, Hurst says that:

6. I believe fluoro-polymer manufacturers must have a minimum standard of QC care due to the greater levels of damage that the by-products of residual monomers can inflict over most ordinary polymers. This minimum standard would include at least an initial determination of the identification of any spurious by-products and amounts of injurious monomers or co-monomers in the initial lab batches and/or initial factory runs with the toll operator. A method of analysis should be available to allow independent checking of the polymer for these products of interest especially in times of emergency. This standard was not met by the manufacturers in any testimony that I read.

(Core Expert Disclosure by Pls., Ex. B, at 5.) As another example, in his affidavit, Hurst says that:

My chemical analysis was performed using accepted scientific methods. I used an ion specific electrode to test for free fluoride ions in the samples. I used infrared spectroscopy to show bonded hydroxyl and carbonyl ester in the batches. I used high performance thin-layer chromatography (HPTLC) to differentiate between the fluoropolymers in the samples. I used thermogravimetry to determine the remaining solids. These are all accepted methods of chemical analysis. The use of HPTLC has been recognized as a proper method to differentiate between weights of polymers, in the Journal of Liquid Chromatography, . . . and

in the differentiation of closely allied substances such as aflatoxins, benzopryene, mycotoxins by the Association of Analytical Chemists, in their publication of Official Methods of Analysis 12th Edition.

(Hurst Aff. ¶ 5.) The Defendants say that, before his affidavit, Hurst never cited to the Journal of Liquid Chromatography or the Official Methods of Analysis 12th Edition. But Hurst only cited to these sources to explain his use of HPTLC testing. And, because Hurst refers to HPTLC testing throughout his expert report, these articles merely elaborate on issues already raised in Hurst's expert report. See Emcore Corp. v. Optium Corp., Civ. A. No. 6-1202, 2008 WL 3271553, at \*4 (W.D. Pa. Aug. 5, 2008) (allowing elaboration of "an opinion/issue previously addressed in [the expert's] report"); Forest Labs., Inc. v. Ivax Pharm., Inc., 237 F.R.D. 106, 113 (D. Del. 2006) (same). The Defendants object to other parts of Hurst's affidavit, but those objections are also without merit and do not require additional discussion. Therefore, Hurst's affidavit should not be excluded.

## 2. Henry Spiller

After careful review of Henry Spiller's expert report, deposition testimony, and affidavit, Spiller's affidavit should not be excluded. Although the statements in Spiller's affidavit are not identical to the statements in his expert report, they "[do] not differ substantially." Rowe Int'l Corp., 586 F. Supp. 2d at 935. For example, in his affidavit, Spiller says that:

[B]ecause we know the product is toxic, it is unethical to expose humans to the product merely for the sake of determining the dose necessary to produce the injury. Consequently, toxicologists look at the histories of people who have been exposed (after the exposure has occurred and the symptoms are already evident) and use our best efforts to estimate the dose, not in exact numbers, but based on an estimate such as “small,” which includes 90 seconds of exposure to a misted product.

(Spiller Aff. ¶ 16.) The Defendants say that, before his affidavit, Spiller never said that the dose necessary to cause injury can be as small as exposure of ninety seconds. But that is exactly what Spiller said during his deposition:

Q. Then you can't say what dose is sufficient, then, can you?

A. We know it's very small. Know it's – you know, 90 seconds of use that caused this clinical in patients.

(Spiller Dep. at 173-74.) This is also consistent with Spiller's expert report:

The spraying time in patients with pulmonary injury in previous outbreaks has been reported to be from as little as seconds to 90 minutes, which is similar to the patients in Stand N Seal outbreak. In my experience we have had respiratory illness in patients who were bystanders with no direct spraying activity, suggesting the exposure dose necessary to produce symptoms is small.

(Core Expert Disclosure by Pls., Ex. C, at 2.) As another example, in his affidavit, Spiller says that:

As I stated during my deposition and referenced above, I did not rely on the chemist expert David Hurst as a basis for reaching any of my conclusions, but his opinions are consistent with the scientific literature and support my conclusions. I surely did not rely “solely” on Mr. Hurst’s opinions in support of any of my opinions.

(Spiller Aff. ¶ 12.) The Defendants say that “this new opinion is belied by [Spiller’s] deposition testimony where he clearly admitted that in determining the size of the Flexipel particles Stand ‘n Seal produced when sprayed, he relied only on Mr. Hurst’s testing.” (Defs.’ Memorandum of Law in Supp. of Their Mot. to Exclude the Aff. of Henry Spiller, at 10.) But that is not what Spiller said during his deposition:

Q. Are you relying in terms of material testing, are you relying solely on the material testing of Stand ‘N Seal that was done by Mr. Hurst in forming your opinions related to Stand ‘N Seal and Flexipel?

A. No.

Q. What other material testing of Stand ‘N Seal have you reviewed and are relying on in forming your opinions related to Stand ‘N Seal or Flexipel?

A. What other material –

Q. Testing – Let me back up. I said did you rely solely on the testing of Stand ‘N Seal or Flexipel done by Mr. Hurst in forming your opinions and you said, “no?”

A. Correct.

Q. All right. What other testing of Stand ‘N Seal or Flexipel have you reviewed in your relying on in forming your opinions?

A. There has been no other testing, it’s from the clinical evidence or from the cases from what I know of the symptoms, but there were no other specific test, besides David Hurst that I know of or that have been provided to me.

Q. All right. Listen carefully.

A. I think in forming my opinion is what I’m answering.

Q. Okay.

A. I’m telling you that there are no other tests, but that’s not solely what I’m relying on for my opinion.

(Spiller Dep. at 65-66.) The Defendants object to other parts of Spiller's affidavit, but those objections are also without merit and do not require additional discussion. Therefore, Spiller's affidavit should not be excluded.

3. Roger Wabeke

After careful review of Roger Wabeke's expert report, deposition testimony, and affidavit, only one sentence of paragraph 14 of Wabeke's affidavit is new. In paragraph 14, Wabeke says that “[a]lthough I have never performed aerosol testing for fluoropolymers, I have conducted aerosol testing for other types of polymers, including asbestos, polyvinyl chloride, polyvinyl butyrate, and polycarbonate among others.” (Wabeke Aff. ¶ 14.) Until his affidavit, Wabeke had never disclosed that he had conducted this type of testing, even though the Defendants explicitly asked him about this issue during his deposition. (Wabeke Dep. at 167-68.) This statement should have been included in Wabeke's deposition testimony or possibly in a supplemental expert report. See Palmer, 2007 WL 2254343, at \*3. Therefore, the one sentence from paragraph 14 of Wabeke's affidavit should be excluded and will not be considered by the Court. See Fed. R. Civ. P. 37(c)(1).

The rest of Wabeke's affidavit, however, should not be excluded. Although the statements in Wabeke's affidavit are not identical to the statements in his expert report, they “[do] not differ substantially.” Rowe Int'l Corp., 586 F. Supp. 2d at 935.

For example, in his affidavit, Wabeke says that “[i]t has been well known by toxicologists for decades that inhalation of respirable size fluoropolymer resin have a toxic effect to the terminal bronchioles and to the alveoli.” (Wabeke Aff. ¶ 6.) The Defendants say that this is a new opinion that was not disclosed in his expert report and during his deposition testimony. But Wabeke did discuss his opinion of how toxicologists treat fluoropolymers during his deposition testimony:

Q. You have not relied upon any animal studies for your opinions here today; is that fair?

A. Well, as I said earlier, over the years, I’ve studied numerous articles in the literature of journals that cross my desk regarding fluoropolymer resins as adverse – as etiologic agents in pulmonary disease in animal models, and specific clinical case reports among workers, the simplest of which would be teflon fume fever, when teflon decomposes at a high temperature. That’s different from the case at hand. But it was a sentinel item, because it clearly showed that there were adverse effects from fluorine containing organic molecules in a polymeric form, and it was an alert. It was an alert to the industrial hygiene community from that point on, and has been since.

(Wabeke Dep. at 41-42.) As another example, in his affidavit, Wabeke says that “[w]hen I was working [at] Ford [Motor Company] and employees were suffering respiratory injuries in connection with the use of an aerosolized waterproofing product, I conducted an in-depth study of this topic.” (Wabeke Aff. ¶ 10.) The Defendants say that Wabeke “did not reference any ‘in-depth study’ of fluoropolymers while at Ford in his expert reports or at his deposition.” (Defs.’

Memorandum of Law in Supp. of Their Mot. to Exclude the Aff. of Roger Wabeke,  
at 8.) But Wabeke did discuss his work at Ford during his deposition:

Q. You've been involved in fluoropolymer cases before?  
A. Yes.  
Q. How many?  
A. My best recall is about seven, seven men who were exposed and developed severe lung disease.  
Q. Was that in relation to litigation?  
A. No.  
Q. Was that in relationship to your work at Wayne State?  
A. No.  
Q. Where was it?  
A. Ford Motor Company.  
....  
Q. So it was the harness that was the product that you believe is the source of the complaints?  
A. Well, it wasn't the harness. The harness was the root cause of recalls and significant issues with stalling problems. We had customer – Ford had customer complaints regarding stalling, and the root cause was determined to be water intrusion somewhere into the harnesses themselves causing cross connections and shorts. And the solution that was selected to protect the harnesses on the recall and with new products was to spray them with a fluoropolymer resins suspended in trichloroethane.

(Wabeke Dep. at 38-39.) Although Wabeke never described his work at Ford as an “in-depth study” until his affidavit, Wabeke is allowed to elaborate. See Emcore Corp., 2008 WL 3271553, at \*4; Forest Labs., Inc., 237 F.R.D. at 113. The Defendants object to other parts of Wabeke’s affidavit, but those objections are also without merit and do not require additional discussion. Therefore, except for the one

sentence from paragraph 14 of Wabeke's affidavit, Wabeke's affidavit should not be excluded.

B. Expert Testimony

The Defendants move to exclude testimony from the Plaintiffs' experts David Hurst, Henry Spiller, and Roger Wabeke. The Defendants say that this testimony should be excluded because it does not meet the requirements for admissible expert testimony. Rule 702 provides that:

A witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based on sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case.

Fed. R. Evid. 702; Daubert v. Merrell Dow Pharm., Inc., 509 U.S. 579, 589 (1993).

The reason for these requirements is to ensure that an expert "employs in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field." Kumho Tire Co., Ltd., v. Carmichael, 526 U.S. 137, 152 (1999). The party offering testimony from an expert must show by a preponderance of evidence that the testimony is admissible. Allison v. McGhan Med. Corp., 184 F.3d 1300, 1306 (11th Cir. 1999). The Court will discuss each expert separately.

1. David Hurst

The Plaintiffs offer the testimony of David Hurst as an expert in analytical chemistry. Hurst was retained to study the chemical makeup of Stand ‘n Seal. Hurst was given eleven samples of various batches of Stand ‘n Seal and was not told whether the batches contained Zonyl or Flexipel. (Hurst Aff. ¶ 4; Core Expert Disclosure by Pls., Ex. B, at 4-6.) Hurst then performed various tests on the samples to determine if any differences existed between the batches of Stand ‘n Seal. (Core Expert Disclosure by Pls., Ex. B, at 4-6.) These tests included the use of ion-selective electrodes (ISE), infrared spectrophotometric comparative analysis, high performance thin-layer chromatography (HPTLC), and thermogravimetric solids determination. (Id.) He was also given the Material Safety Data Sheets for Zonyl and Flexipel, and the deposition testimony of Defendants’ experts Bruce Baker, Jeffrey Alender, and Larry Brotherton. (Id.) In his expert report, Hurst provided nine opinions based on these tests and documents. Hurst’s opinions include that Flexipel and Zonyl are chemically different, there is variability among the batches of Stand ‘n Seal with Flexipel, the variability among the batches of Stand ‘n Seal with Flexipel indicates quality control problems, Stand ‘n Seal with Flexipel produces respirable size particles, and Stand ‘n Seal would have been safer as a brush on product. (Id., at 6-8.)

After careful review of Hurst's expert report, deposition testimony, and affidavit, only one of Hurst's opinions is questionable. In his expert report, Hurst's ninth opinion is that Stand 'n Seal would have been safer as a brush on product:

I believe that much of the problem with this product could have been avoided if the product could have been recommended as a brushed on product. This would be a much safer use of the product even if were to be found defective in some way.

Reason:

The films would have been confined to a relatively small area with no aerosolization of any dangerous products, either gaseous or particulate.

(Core Expert Disclosure by Pls., Ex. B, at 5.) But, during his deposition, Hurst admitted that this opinion requires scientific testing and that he had not done any scientific testing of Stand 'n Seal as a brush on product:

Q. Now, I'm going to go back to your scientific basis. In order to make a statement that the brushed-on product with Flexipel would be safer, you would have to actually do some testing, some scientific testing, in order to come up with that, correct?

A. Yes, probably so.

Q. And so you really can't make that opinion that a brushed-on or roller application of Stand 'N Seal with Flexipel is actually a safe product until that testing was done, correct?

A. That's true.

(Hurst Dep. at 141.) Hurst has now done the testing necessary to support this opinion.

Therefore, his testimony is admissible under Rule 702.

The rest of Hurst's testimony also should not be excluded. Hurst is qualified to testify about the chemical components of Stand 'n Seal. He is the owner and

Director of Hurst Research, a private consulting laboratory in Georgia. (Hurst Aff. ¶ 3.) Hurst has worked in the field of analytical chemistry for more than forty years and has specialized in identification of unknown chemical products. (*Id.*) Hurst has published articles in peer-reviewed publications. (*Id.*) His work has included preparing field testing reports of nuclear power reactors for the Nuclear Regulatory Commission, the Environmental Protection Agency, and the Georgia Environmental Protection Division. (*Id.*) Hurst's work has also included reports on security inks for the Lottery Commissions in California, New York, and Massachusetts. (*Id.*) His opinions regarding analytical chemistry have been accepted by state and federal courts. (*Id.*)

The Defendants say that Hurst merely attended classes but did not earn a college degree from the Georgia Institute of Technology. But a college degree is not a requirement for expert testimony. Rule 702 clearly contemplates that “experience in a field may offer another path to expert status.” United States v. Frazier, 387 F.3d 1244, 1261-62 (11th Cir. 2004); Birge v. Dollar Gen. Corp., No. 04-2531, 2006 WL 5175758, at \*10 (W.D. Tenn. Sept. 28, 2006) (allowing testimony based on expert’s thirty-seven years of experience in private security). The Defendants also say that “Hurst does not even hold himself out as a chemist. He describes his field as ‘chemical analysis.’” (Defs.’ Memorandum of Law in Supp. of Their Mot. to Exclude

the Testimony of David Hurst, at 6.) But analytical chemistry is a legitimate sub-discipline of chemistry. See American Chemical Society, Division of Analytical Chemistry, <http://www.analyticalsciences.org/education.php> (last visited May 4, 2009) (“Many household products, fuels, paints, pharmaceuticals, etc. are analyzed by the procedures developed by analytical chemists before being sold to the consumer.”). The Defendants also say that Hurst does not have prior experience with fluorinated acrylic polymers or the industrial scale polymerization process. But Hurst has said that he worked on fluorinated acrylic polymers in 2007 before being retained for this case. (Hurst Aff. ¶ 6; Hurst Dep. at 159-60.) Even if he had not worked with fluorinated acrylic polymers before, Hurst’s general background in analytical chemistry is sufficient.

Hurst’s testimony is based on sufficient facts and data. Hurst based his opinions on tests he conducted on eleven samples of various batches of Stand ‘n Seal. (Hurst Aff. ¶ 4; Core Expert Disclosure by Pls., Ex. B, at 4-6.) He also based his opinions on the Material Safety Data Sheets for Zonyl and Flexipel, and the deposition testimony of Defendants’ experts Bruce Baker, Jeffrey Alender, and Larry Brotherton. (Core Expert Disclosure by Pls., Ex. B, at 4-6.) The Defendants say that Hurst’s testimony is not based on sufficient facts or data because Hurst asked for but did not

receive additional information about Flexipel. But this does not mean that his opinions were not based on sufficient facts or data. As Hurst explains:

I had enough information when I issued my report to reach the conclusions I did. I have consistently stated that if I had been given additional information about Flexipel S-22WS and the manufacturing process I could provide additional opinions and reaching the opinions I did would have been easier. The opinions I have given, however, are within a reasonable degree of scientific probability based on the testing and my knowledge, experience, and training they are more likely than not. During my deposition, I was asked questions that would expand on the opinions stated in my report, and I refused to do so, because what I have stated in my report is what is based on a reasonable degree of probability.

(Hurst Aff. ¶ 7.)

Hurst's testimony is also the product of reliable principles and methods, and he has applied those principles and methods reliably to the facts of this case. Hurst's tests included the use of ion-selective electrodes (ISE), infrared spectrophotometric comparative analysis, high performance thin-layer chromatography (HPTLC), and thermogravimetric solids determination. (Core Expert Disclosure by Pls., Ex. B., at 4-6.) These are all accepted methods of chemical analysis. (Hurst Aff. ¶¶ 5, 8.) The Defendants say that there are better methods of chemical analysis that Hurst did not use. (Hurst Dep. at 230-32.) But that does not mean that the methods of chemical analysis that Hurst did use are unreliable. Cf. Heller v. Shaw Indus., Inc., 167 F.3d 146, 152-53 (3d Cir. 1999) ("[E]ven if the judge believes . . . that there are some flaws

in the scientist's methods, if there are 'good grounds' for the expert's conclusion, it should be admitted.").

The Defendants also say that, during his deposition, Hurst conceded that many of his opinions were unreliable. But the Defendants often overstate what Hurst said during his deposition. For example, Hurst's third opinion in his expert report is that:

I believe that the [Flexipel] 22WS batches have wider Mw [(molecular weight)] spreads than Zonyl 225 and are indicative of a need for monomer, dimer and oligomer cleanup.

Reason:

The HPTLC data shows peak broadening above and below main peak for only the [Flexipel] 22WS samples.

(Core Expert Disclosure by Pls., Ex. B., at 4.) The Defendants say that, during his deposition, Hurst conceded that this opinion is unreliable:

Q. . . . [D]o you hold opinion number three here, "I believe that [Flexipel] 22WS batches have wider Mw [(molecular weight)] spreads than Zonyl 225 and are indicative of a need for monomer, dimer, and oligomer cleanup." Do you hold that opinion?

A. Yes.

Q. And we've discussed all of your reasons for that already, correct?

A. Yes.

Q. And we – we talked about you don't have specific knowledge about the cleanup, the percentage of monomer, dimer, oligomer at any stage, so that is really just speculation at this particular juncture, correct?

A. Yes.

(Hurst Dep. at 128). But Hurst did not abandon his opinion that his tests showed that there is variability among the batches of Stand 'n Seal with Flexipel, including wider molecular weight spreads. Hurst also did not abandon his opinion that one possible

explanation for the variability is that the manufacturer of Flexipel failed to use adequate quality control measures (such as monomer, dimer, and oligomer cleanup).

Instead, Hurst only said that, based on the information he received, he cannot say whether the manufacturer of Flexipel did actually use adequate quality control measures. As Hurst explains:

Based on the information I was provided about the polymerization process of Flexipel S-22WS, there was not a test for residual monomers. I was not, however, provided details of the polymerization process. Consequently, it is possible that such a quality control measure exists in the process. My opinions in this case are that a reasonable polymer producer will have quality control procedures in place to ensure the reduction of residual monomers, especially when dealing with [fluoropolymers] that present a significant risk of harm. I never stated that the manufacturers of Flexipel S-22WS did or did not have the necessary quality control procedures in their polymerization process. I have merely stated that from the testimony I have read and what I have been provided, no such quality control procedure exists. The motions attempting to exclude my opinions appear to misunderstand my opinions, in this regard. My opinions are as to what a prudent manufacturer of fluoropolymers will do in the polymerization process. I have not attempted to provide an opinion within a reasonable degree of scientific probability that the manufacturers failed to have adequate quality control processes in place, because that is a factual dispute based on testimony of witnesses, not scientific analysis.

(Hurst Aff. ¶ 11.) As another example, Hurst's fourth opinion in his expert report is that:

I believe that the Stand 'n Seal cans are using spray nozzles that produce 20-50micron wet spray particles but as they dry, there is the probability that the particles will shrink to 2-5micron size which, as I am led to understand by toxicologists, are respirable.

Reason:

The solutions of all batches of Stand 'n Seal that I have tested by Thermogravimetric analysis indicate that they have nominal weight percent solids of approximately 1%. If the wet particle spray is 20-50micron, then a 90% dried particle would have approximately 10% the volume of the wet particle. This was mathematically derived.

(Core Expert Disclosure by Pls., Ex. B., at 4.) The Defendants say that, during his deposition, Hurst conceded that this opinion is unreliable:

Q. If we can go to opinion number four, sir. We talked about in opinion number four, spray nozzles produce 20- to 50-micron wet spray particles. Where do you get that information?

A. Seems like it was mentioned in some depositions.

Q. Okay.

A. From ITC or somewhere in there.

Q. Yes, sir. But from a scientific standpoint, you're not certain – you're not reasonably certain of this particular statement, correct?

A. I'm not reasonably and scientifically stating that as a fact.

Q. All right. And you're not saying that there's a probability of shrinkage because we don't know what it starts with to get to the strength – the strength it is, correct, from a scientific standpoint.

A. Right.

(Hurst Dep. 128-29.) But Hurst did not abandon his opinion that if Stand 'n Seal produces twenty to fifty micron size wet spray particles, those particles, as they dry, will shrink to two to five micron size particles, which toxicologists say are respirable size particles. Instead, Hurst only said that he cannot say whether Stand 'n Seal actually produces twenty to fifty micron size wet particles. As Hurst explains:

My fourth opinion in my report is merely based on a mathematical calculation of reduced particle size based on information provided by the defendants about the size of the particles sprayed from Stand 'n Seal

with Flexipel S-22WS. My mathematical calculations are given within a reasonable degree of scientific probability. I am not giving the opinion that Stand ‘n Seal with Flexipel S-22WS produces particles 20-50 microns in size. I am getting that information from the defendant’s tests.

(Hurst Aff. ¶ 10.) Hurst’s opinion would not be relevant if the Defendants’ tests did not actually show that Stand ‘n Seal produces twenty to fifty micron size wet particles, but the Defendants do not dispute those numbers. The Defendants object to other parts of Hurst’s testimony, but those objections similarly overstate what Hurst said during his deposition and do not require additional discussion. Therefore, Hurst’s testimony should not be excluded.

## 2. Henry Spiller

The Plaintiffs offer the testimony of Henry Spiller as an expert in toxicology. Before being retained in this case, Spiller was already working on Stand ‘n Seal with Flexipel. When the outbreak of injuries associated with Stand ‘n Seal occurred in 2005, Spiller was the Director of the Kentucky Regional Poison Control Center. (Spiller Aff. ¶ 5.) In that capacity, he was contacted by physicians to discuss treatment options for patients who had reported respiratory problems that occurred shortly after using Stand ‘n Seal. (*Id.*) Spiller became personally involved in the clinical analyses of some of these patients. (*Id.*) Spiller also became aware that other poison control centers were receiving similar contact from physicians. (*Id.*) Spiller came to “the conclusion that it was more likely than not something in the can of Stand

N Seal was causing these injuries.” (*Id.*) Spiller based this conclusion on the striking similarity of the patients’ exposure conditions and injuries, and the strong temporal association between the use of Stand ‘n Seal and the occurrence of injuries. (*Id.*) Although at the time Spiller did not know the exact ingredients in Stand ‘n Seal, Spiller also came to the conclusion that “this product more likely than not contained a fluoropolymer.” (Spiller Aff. ¶ 7.) Spiller based this conclusion on the similarity between this outbreak and past outbreaks that occurred because of other waterproofing sprays that contained fluoropolymers. (*Id.*)

In late 2005 or early 2006, Spiller became involved with a team of physicians and toxicologists that studied the outbreak of injuries associated with Stand ‘n Seal. (Spiller Aff. ¶ 8.) They reviewed more than thirty cases and concluded that “the users (and some bystanders) of Stand N Seal were experiencing respiratory injuries as a result of their exposure to Stand N Seal and that their injuries were more likely than not caused by the fluoropolymer resin in the product.” (*Id.*) Their conclusions were based on:

[T]he strong temporal association between the exposure and the acute onset of respiratory symptoms, the fact the patients were diagnosed with chemical pneumonitis (lower lung injuries, for which the particles had to have been less than 10 microns in diameter), the fact that there were no other components in Stand N Seal with Flexipel S-22WS that could reach respirable size (absent huffing, of which there was no evidence), no other consistent potential causes for the class of patients (no other gases being released, no hydrocarbons being aspirated), the fact that the

patients were presenting consistent symptoms across the nation identified with the same product, previous research and studies showing waterproofing products with fluoropolymers had caused similar outbreaks and similar respiratory injuries throughout the past few decades, the fact these previous outbreaks also followed shortly after the products underwent a change to the fluoropolymer, and the fact that the outbreak began and ended in conjunction with the introduction and removal of the product from the market.

(Id.) An abstract describing the team's study and results was presented to the 2006 North American Congress of Clinical Toxicology Annual Meeting. See G. P. Daubert, Henry A. Spiller, B. Crouch, S. A. Seifert, K. Simone, P. Patel & S. Smolinske, Pulmonary Toxicity Following Exposure to Waterproofing Grout Sealer, 44 Clinical Toxicology 625, 668-69 (2006). After being retained in this case, Spiller reviewed additional information about Stand 'n Seal, including additional patient histories, testimony from some of representatives of the Defendants, testimony from some of the Plaintiffs, and the opinions of other experts. Spiller says that "[a]ll of this information confirms my initial opinions that I reached before I was retained as an expert in this litigation." (Spiller Aff. ¶ 9.)

After careful review of Spiller's expert report, deposition testimony, and affidavit, Spiller's testimony should not be excluded. Spiller is qualified to testify about the potential toxicity of Stand 'n Seal. He has been the Director of the Kentucky Regional Poison Control Center since 1993. (Spiller Aff. ¶ 3.) Spiller has been certified in toxicology by the American Board of Applied Toxicology and is

registered as a professional nurse. (*Id.*) He is a member of the American Association of Poison Control Centers, the American Academy of Clinical Toxicology, the American Board of Applied Toxicology, the Society of Forensic Toxicologists, the American College of Forensic Examiners, and the Toxicological Historical Society. (*Id.*) Spiller is also on the editorial board of *The Forensic Examiner* and *The Open Forensic Science Journal*, and has been a reviewer for publication of articles in *Clinical Toxicology*, *Journal of Medical Toxicology*, and *Journal of Occupational Medicine and Toxicology*. (*Id.*) Spiller has over 220 publications regarding toxicology. The Defendants do not dispute Spiller's qualifications.

Spiller's testimony is based on sufficient facts and data. Even before being retained in this case, Spiller was working on Stand 'n Seal with Flexipel. Spiller was personally involved in the clinical analyses of patients who had reported respiratory problems that occurred shortly after using Stand 'n Seal. Spiller was also involved with a team that studied the outbreak of injuries associated with Stand 'n Seal, including reviewing more than thirty cases of suspected injuries. After being retained in this case, Spiller received additional information about Stand 'n Seal. The Defendants do not dispute that Spiller's testimony is based on sufficient facts and data.

Spiller's testimony is also the product of reliable principles and methods, and Spiller has applied those principles and methods reliably to the facts of this case. As explained above, Spiller reached most of his opinions about Stand 'n Seal even before he was retained in this case. His work on Stand 'n Seal arose naturally out of his duties as Director of the Kentucky Regional Poison Control Center. This fact, by itself, suggests that Spiller's testimony is reliable:

That an expert testifies based on research he has conducted independent of the litigation provides important, objective proof that the research comports with the dictates of good science. For one thing, experts whose findings flow from existing research are less likely to have been biased toward a particular conclusion by the promise of remuneration; when an expert prepares reports and findings before being hired as a witness, that record will limit the degree to which he can tailor his testimony to serve a party's interests. Then, too, independent research carries its own indicia of reliability, as it is conducted, so to speak, in the usual course of business and must normally satisfy a variety of standards to attract funding and institutional support. Finally, there is usually a limited number of scientists actively conducting research on the very subject that is germane to a particular case, which provides a natural constraint on parties' ability to shop for experts who will come to the desired conclusion. That testimony is proffered by an expert is based directly on legitimate, preexisting research unrelated to the litigation provides the most persuasive basis for concluding that the opinions he expresses were "derived by the scientific method."

Daubert v. Merrell Dow Pharms., Inc., 43 F.3d 1311, 1317 (9th Cir. 1995); see also Fed. R. Evid. 702 advisory committee note (2000).

Spiller's principles and methods are also consistent with the Bradford Hill criteria, "which are nine factors widely used in the scientific community to assess

general causation.” Gannon v. United States, 292 Fed. Appx. 170, 173 (3d Cir. 2008) (unpublished).<sup>2</sup> The nine factors are (1) the strength of the association, (2) the consistency of the association, (3) the specificity of the association, (4) the temporal relationship of the association, (5) whether there is a dose-response relationship, (6) whether causation is biologically plausible, (7) the coherence of the association, (8) the presence of experimental evidence, and (9) evidence by analogy. (Hurst Aff., Ex. C.) The Defendants say that Spiller only relied on the temporal relationship of the association in forming his opinions. But, after reviewing Spiller’s expert report, deposition testimony, and affidavit, it is clear that Spiller relied on more than just the temporal relationship of the association. Indeed, Spiller relied on all of the factors except for the dose-response relationship. (See Hurst Aff. ¶ 8.) That Spiller’s principles and methods are consistent with the Bradford Hill criteria suggests that his testimony is reliable. See In re Viagra Prods. Liab. Litig., 572 F. Supp. 2d 1071, 1081 (D. Minn. 2008).

The Defendants say that Spiller’s testimony is unreliable because Spiller did not establish a dose-response relationship. “The dose-response relationship is a relationship in which a change in amount, intensity, or duration of exposure to an

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<sup>2</sup>As the Defendants point out, Spiller did not explicitly rely on the Bradford Hill criteria. But that is irrelevant to whether Spiller’s principles and methods are consistent with the Bradford Hill criteria.

agent is associated with a change – either an increase or decrease – in risk of disease.”

McClain v. Metabolife Int’l, Inc., 401 F.3d 1233, 1241-42 (11th Cir. 2005) (internal quotation marks omitted). “The expert who avoids or neglects this principle of toxic torts without justification casts suspicion on the reliability of his methodology.” Id. at 1242. But Spiller did not neglect the dose-response relationship without justification. He explained:

[T]oxicologists are often required to render opinions regarding toxicity and causation of injuries without being able to quantify the dose as an exact number. Just as I estimated the necessary dose in this case as small, toxicologists often estimate the doses necessary to cause injury to humans when they are dealing with toxicity determined from actual human exposures. This is especially true when the exposure is to something inhaled or encountered in inconsistent amounts, as opposed to medicines to which the exposure can be more accurately measured. When consumers who are unaware of the potential for injury sustain injuries because of exposure to a product, there is no way to measure the exact dose to which they were exposed. . . . Consequently, toxicologists look at the histories of people who have been exposed (after the exposure has occurred and the symptoms are already evident) and use our best efforts to estimate the dose, not in exact numbers, but based on an estimate such as “small,” which includes 90 seconds of exposure to a misted product.

(Spiller Aff. ¶ 16.) Spiller’s explanation is consistent with the scientific literature regarding respiratory injuries from fluoropolymer resins. See David Vernez et al., Acute Respiratory Syndrome After Inhalation of Waterproofing Sprays, 3 J. Occupational & Environmental Hygiene 250, 259 (2006) (“The lack of dose-response correlation with both perceived severity and clinical indicators suggests that (a) it is

not possible to define a threshold dose below which the incriminated sprays could be safely used, and (b) some indirect or complex mechanism(s) predominated in the occurrence of the respiratory disease.”). That Spiller did not establish a dose-response relationship does not mean that his testimony is unreliable. See Hardyman v. Norfolk & W. Ry. Co., 243 F.3d 255, 265 (6th Cir. 2001); Westberry v. Gislaved Gummi AB, 178 F.3d 257, 264 (4th Cir. 1999).

The Defendants also say that Spiller’s testimony is unreliable because Spiller did not establish that Stand ‘n Seal with Flexipel produces respirable size particles. But Spiller did say in his export report that “[t]he recalled Stand N Seal product produced airborne respirable particles.” (Core Expert Disclosure by Pls., Ex. C, at 3.) Spiller based this conclusion, in part, on the testing and mathematical calculations by David Hurst. The Defendants say that, during his deposition, Hurst conceded that his opinion on this issue was unreliable. But, as explained above, the Defendants overstate what Hurst said during his deposition. Hurst’s testimony is reliable, and Spiller is entitled to rely on Hurst’s tests and mathematical calculations. Even if Hurst’s opinion on this issue were unreliable, Spiller also based his conclusion on the extensive clinical evidence. As Spiller has explained in deposition testimony and affidavit, many patients were diagnosed with lower lung injuries, specifically chemical pneumonitis. (Spiller Aff. ¶ 8.) Because lower lung injuries of this nature

are only caused by particles of one to ten micron size, and because there were no other components of Stand ‘n Seal that could produce particles of this size, Spiller says that “[i]t is almost beyond doubt” that Stand ‘n Seal with Flexipel produces respirable size particles. (Spiller Aff. ¶ 12.) While this is not the most conclusive evidence that Stand ‘n Seal with Flexipel produces respirable size particles, it is sufficient to show that Spiller’s testimony is admissible. See Heller, 167 F.3d at 152-53 (“[E]ven if the judge believes . . . that there are some flaws in the scientist’s methods, if there are ‘good grounds’ for the expert’s conclusion, it should be admitted.”).

The Defendants also say that Spiller’s testimony is unreliable because Spiller relies on scientific articles presenting case reports of exposure to fluoropolymers in waterproofing sprays. It is true that, “while they may support other proof of causation, case reports alone ordinarily cannot prove causation.” Rider v. Sandoz Pharm. Corp., 295 F.3d 1194, 1199 (11th Cir. 2002). But Spiller does not rely on those case reports alone to prove causation. Spiller also relies on his personal clinical experience with Stand ‘n Seal with Flexipel. His clinical experience showed a striking similarity of the patients’ exposure conditions and injuries, and a strong temporal association between the use of Stand ‘n Seal and the occurrence of injuries. The strong temporal association in this case is “powerful evidence of causation,” and alleviates some of the concerns normally associated with reliance on case reports.

Bonner v. ISP Techs., Inc., 259 F.3d 924, 931 (8th Cir. 2001).<sup>3</sup> Indeed, this is the same conclusion reached by one of the scientific articles presenting case reports of exposure to fluoropolymers in waterproofing sprays:

One could argue that some subjects may have wrongly attributed their symptoms to aerosol exposure, whereas the symptoms had in fact another origin, such as a viral infection. Although such a bias cannot be completely ruled out, we believe that the causality between aerosol exposure and symptoms appears extremely likely in most, if not all, cases, in view of the acute onset of symptoms after exposure; the clear temporal relationship between exposure and symptom occurrence; the absence of pre-existing diseases in most cases; the rapid improvement within days after the exposure; and the absence of any alternative explanation for the symptoms detected by the questionnaire.

Vernez et al., supra, at 253.

Lastly, the Defendants say that Spiller's testimony is unreliable because Spiller relies on the adverse effects of other types of fluoropolymers to support his opinion that Flexipel is the cause of the Plaintiffs' injuries. The Defendants cite to McClain, which in turn cites to an article by Dr. David Eaton, a toxicologist and Professor of Environmental and Occupational Health Sciences at the University of Washington. McClain, 401 F.3d at 1242. In that article, Dr. Eaton says that "even small differences

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<sup>3</sup>In many cases, a temporal association is not significant. See, e.g., McClain, 401 F.3d at 1243. But, "[u]nlike health effects manifesting months, years, or decades after exposure and which could be attributed to many different actual causes, the adverse symptoms here manifested immediately after exposure." Rowland v. Tile Perfect, Inc., No. CV-2005-016296 (Ariz. Super. Ct. Apr. 1, 2009).

in chemical structure can sometimes make very large differences in the type of toxic response that is produced.” David L. Eaton, Scientific Judgment and Toxic Torts - A Primer in Toxicology for Judges and Lawyers, 12 J.L. & Pol'y 5, 10 (2003). But, in that same article, Dr. Eaton also says that “[s]ometimes chemicals of a common type cause a generalized adverse response. For example, nearly all organic solvents from petroleum products . . . share some (but not all) symptoms in common: ‘defatting’ of the skin following dermal exposure, and central nervous system depression . . . following relatively high levels of inhalation exposure.” Id. In sum, sometimes chemicals of a common type will have similar effects, and sometimes they will not. Because of the strong similarity between the outbreak of injuries associated with Stand ‘n Seal and past outbreaks of injuries associated with other fluoropolymers, it is reasonable to believe that fluoropolymers fall into the category of chemicals that have similar effects. Therefore, Spiller’s testimony should not be excluded.

### 3. Roger Wabeke

The Plaintiffs offer the testimony of Roger Wabeke as an expert in toxicology and industrial hygiene. Wabeke’s foundational opinion is that:

SNS with Flexipel S-22WS was improperly formulated and improperly engineered for use as a product to be dispensed as an aerosol spray. The ingredients are too hazardous and toxic to be dispensed as an aerosol that is inhaled as a respirable mist. Ingredients include gas propellants (propane and iso-butane), an odorizing agent, organic solvents, and the active ingredient: fluoropolymer resins. Organic solvents evaporate

quickly as inhalable vapors. Odorants are typically less volatile and linger in the air with mist particles becoming small over time. The fluoropolymer resin aerosol particles are non-volatile and become smaller over time as organic solvent vapors in which the resin is dissolved/suspended evaporate and, thus, they have a greater ability to intrude into deeper anatomical regions of the lungs, specifically the bronchioles and the alveoli. SNS has such profound designs and warning defects that it must not have been marketed to dispensed and applied as a gas propellant aerosol and mist. Absent toxicological data, there is no safe inhalation dose for this product.

(Core Expert Disclosure by Pls., Ex. E, at 2-3.) Wabeke came to his opinions after studying numerous documents, including Material Safety Data Sheets for Zonyl and Flexipel, product recall notices, poison control press releases, and deposition transcripts. (Id., at 2.) Wabeke also relied on:

[His] studies as a graduate student, [his] personal experience regarding injuries that were sustained by workers at Ford Motor Company where [he] was an industrial toxicologist, in [his] work and discussions with toxicologists over the years, and from [his] knowledge of the studies, testing, and publications that have addressed fluoropolymer resins that fluoropolymer resins present inhalation health hazards.

(Wabeke Aff. ¶ 6.)

After careful review of Wabeke's expert report, deposition testimony, and affidavit, none of Wabeke's testimony should be excluded. Wabeke is qualified to testify about the potential toxicity of Stand 'n Seal. He is the President of Chemical Risk Management and Director of Industrial Hygiene and Environmental Toxicology at Wayne State University School of Medicine. (Wabeke Aff. ¶ 3.) Wabeke has

taught toxicology since 1987. Before 1987, Wabeke was an industrial hygienist at Ford Motor Company, including serving for ten years as the Supervisor of Industrial Hygiene. He is a registered licensed industrial hygienest by the Illinois Environmental Protection Agency. Wabeke is also a registered professional engineer in chemical engineering. Wabeke is board-certified in the Comprehensive Practice of Industrial Hygiene and Hazardous Materials Management. He has published articles in numerous peer-reviewed scientific journals in the field of toxicology and industrial hygiene. Wabeke has also published a book on industrial hygiene. The Defendants say that Wabeke is not qualified because “he has never developed, made, or designed a chemical formula for a fluoropolymer, and because “he has never written anything in the peer reviewed literature on fluoropolymers.” (Def.’s Memorandum of Law in Supp. of Mot. to Exclude Roger Wabeke’s Testimony, at. 13.) But the Defendants do not say why Wabeke must have done those things in order to testify about the potential toxicity of Stand ‘n Seal. His general experience in toxicology and industrial hygiene, along with his prior experience with fluoropolymers, is sufficient.

Wabeke’s testimony is also based on sufficient facts and data. Wabeke came to his opinions after studying numerous documents, and he relied on his prior understanding of fluoropolymers. The Defendants say that Wabeke’s testimony is not based on sufficient facts or data because he did not perform any toxicity testing of

Flexipel. But “[a] toxicologist is not required to have specific testing of every final product in order to render opinions regarding toxicity of that product, because toxicity will often be based on the ingredients of the final product. In this case . . . Flexipel contains a fluoropolymer resin.” (Wabeke Aff. ¶ 6.)

Wabeke’s testimony is also the product of reliable principles and methods, and he has applied those principles and methods reliably to the facts of this case. Wabeke’s principles and methods are consistent with the Bradford Hill criteria. As Wabeke explains:

A toxicologist, when presented with a cluster, initially looks at three things to assist in determining causation: (1) geography; (2) adverse health outcomes; and (3) occupation. In this case, the patterns transcended geography and occupation. The adverse health outcomes, however, showed the people were performing common conduct (using a spray-on waterproofing grout sealant), had common exposure (use of product for several minutes), had common acute onset of symptoms (within a few minutes to a few hours), and had similar respiratory injuries. This is consistent with the Criteria for the Occupational and/or Environmental-Relatedness of Disease, which is based on the Bradford Hill criteria.

(Wabeke Aff. ¶ 7.) That Wabeke’s principles and methods are consistent with the Bradford Hill criteria suggests that his testimony is reliable. See In re Viagra Prods. Liab. Litig., 572 F. Supp. 2d at 1081. The Defendants say that Wabeke’s testimony is not reliable for many reasons, including that Wabeke did not establish a dose-response relationship, did not establish that Stand ‘n Seal with Flexipel produces

respirable size particles, and relies on the adverse effects of other types of fluoropolymers to support his opinions. But these arguments are essentially the same arguments that the Defendants made against Henry Spiller's testimony. Those arguments have already been addressed, and so it is not necessary to do so again here. Therefore, Wabeke's testimony should not be excluded.

### C. General Causation

The Defendants move for summary judgment on general causation for all of the claims asserted by the Plaintiffs. "General causation is concerned with whether an agent increases the incidence of disease in a group and not whether the agent caused any given individual's disease. Thus, in this case, Plaintiffs' experts must offer reliable opinions about [Stand 'n Seal with Flexipel's] general toxicity for the harm Plaintiffs allege . . ." McClain, 401 F.3d at 1239 (citations and internal quotation marks omitted). As discussed above, the Plaintiffs' experts David Hurst, Henry Spiller, and Roger Wabeke have provided reliable opinions that Stand 'n Seal with Flexipel causes respiratory injuries of the types suffered by the Plaintiffs. The Defendants say that, even if their motions to exclude are denied, they are still entitled to summary judgment on general causation. But most of the Defendants' arguments on general causation simply restate their arguments that the testimony of the Plaintiffs' experts is unreliable.

The Defendants do have two arguments for summary judgment that require additional discussion. First, the Defendants say that their own experts, Dr. William Longo and Mark Rigler, have conducted tests on Flexipel that show that it is impossible to inhale Flexipel from a can of Stand ‘n Seal. But the Plaintiffs have pointed out weaknesses of those tests that demonstrate that genuine issue of material fact exists as to whether it is possible to inhale Flexipel from a can of Stand ‘n Seal. For example, “the machine they used to test for fluoropolymer resin has wholes 5 microns in diameter, so particles of fluoropolymer resin that were 5 microns or smaller (exactly the size that is causing these injuries) would not have been registered by their equipment.” (Pls.’ Resp. to Defs.’ Mot. for Summ. J. on the Issue of General Causation, at 11-12.) As another example, “the test fails to replicate how a consumer would use the product, because the test protocol was conducted contrary to the instructions on the can.” (*Id.*, at 12.)

Second, the Defendants say that it is illogical for the Plaintiffs to say that Stand ‘n Seal with Flexipel causes injuries because it contains a fluoropolymer, when the Plaintiffs also concede that Stand ‘n Seal with Zonyl also contains a fluoropolymer but did not cause any injuries. But the difference between Stand ‘n Seal with Flexipel and Zonyl has to do with respirable size particles, not toxicity. As another trial court that has dealt with this issue explains:

[The] Plaintiffs' theory of harm is that, during spray application, very small molecules of Flexipel (less than 10 microns) become airborne and entered [the] Plaintiffs' lungs, causing respiratory symptoms. If the molecular weight of Flexipel varied more than the molecular weight of Zonyl or the molecular weight of Flexipel was on average lower than that of Zonyl, there could conceivably be more Flexipel molecules in the sub-10 micron range during spray application than with Zonyl. Under this theory, the likelihood of the sub-10 micron fluoropolymer molecules entering the lungs is reasonably higher in [Stand 'n Seal] with Flexipel than in [Stand 'n Seal] with Zonyl.

Rowland, No. CV-2005-016296 (Ariz. Super. Ct. Apr. 1, 2009). This theory is supported by the tests conducted by David Hurst which indicated that batches of Stand 'n Seal with Flexipel had wider molecular weight spreads than Zonyl and were not subject to adequate quality control. This theory is also supported, to a limited extent, by the clinical work of Henry Spiller which indicated that the types of injuries suffered by patients demonstrate that Stand 'n Seal with Flexipel produces particles of one to ten micron size. This, of course, does not mean that there is no merit to the Defendants' arguments. It simply means that the Defendants have not shown that there is no genuine issue of material fact as to general causation. At this stage of the litigation, the Plaintiffs do not have to explain why Zonyl does not cause injury and Flexipel does. Therefore, the Defendants are not entitled to summary judgment.

#### IV. Conclusion

For the reasons stated above, the Defendants' Motion for Summary Judgment on the Issue of General Causation [Doc. 1367] is DENIED; the Defendants' Motions

to Exclude the Testimony of David Hurst [Doc. 1438, 1850] are DENIED; the Defendants' Motions to Exclude the Testimony of Henry Spiller [Doc. 1763, 1851] are DENIED; the Defendant's Motion to Exclude the Testimony of Roger Wabeke [Doc. 1852] is DENIED; the Defendants' Motion to Exclude the Affidavit of Henry Spiller [Doc. 2098] is DENIED; the Defendants' Motion to Exclude the Affidavit of David Hurst [Doc. 2103] is GRANTED IN PART and DENIED IN PART; and the Defendants' Motion to Exclude the Affidavit of Roger Wabeke [Doc. 2107] is DENIED.

SO ORDERED, this 9 day of June, 2009.

/s/Thomas W. Thrash  
THOMAS W. THRASH, JR.  
United States District Judge